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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/150,947	09/10/98	KAEMPFER R	A31967-PCT-U

EXAMINER	
NAVARRO, A	
ART UNIT	**PAPER NUMBER**
1645	16

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DATE MAILED: 03/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/150,947	Applicant(s) Kaempfer et al
	Examiner Mark Navarro	Group Art Unit 1645

☒ Responsive to communication(s) filed on *Jan 5, 2001*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *50-84* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *50-84* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Applicant's amendment filed on January 5, 2001 (Paper Number 15) has been received and entered. Consequently claims 50-84 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 50-64 and 76-84 under 35 U.S.C. 112, second paragraph, as being vague and indefinite for using the term "substantially homologous" is maintained.

Applicant's are asserting that the claims provide sufficient definition of the peptides by requiring that the purified and isolated peptides correspond to a particular defined region/domain of pyrogenic toxins that forms the "central turn" of such molecules indicates the meets and bounds of the invention. Applicant's further assert that the claimed peptides must be substantially homologous to this region/domain. Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view that the metes and bounds of forming a "central turn" are not set forth. Furthermore, at what level is a peptide "substantially homologous" to one that forms a "central turn" (i.e., 99%, 90%, 50%, etc.)? Without a clear definition as to the metes and bounds of the term "substantially homologous" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

2. The rejection of claims 50-84 under 35 U.S.C. 112, second paragraph, as being vague and indefinite for using the term "derivatives" is withdrawn.

Claim Rejections - 35 USC § 102

3. The rejection of claims 50-84 under 35 U.S.C. 102(b) as being anticipated by Tseng et al (Infection and Immunity 63 (8):2880-2885, Aug 1995) is maintained.

Applicant's are asserting that Tseng et al never isolated any peptides corresponding to a particular domain of SEB as in the present invention, nor tested the ability of such isolated peptides themselves to inhibit SEB and other toxin-mediated activities, nor produced antibodies to the specific peptide that also inhibit toxin-mediated T cell activation, as in the present invention. Applicant's further assert that Tseng et al treated SEB toxin (full length protein) with formalin to produce the toxoid used for immunization, and that the full length protein comprises the region that binds to the T-cell receptor or to MCH class II molecules as indicated in Tseng et al page 2884. Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view of the teaching of Tseng et al. Applicant's have acquiesced that Tseng et al disclose of a full length protein, from which Applicant's are attempting to claim certain peptides. However, Applicant's claims are not commensurate in scope with Applicant's assertions. Applicant's claims recite an isolated and purified peptide "having an amino acid sequence substantially homologous to an amino acid sequence..." The full length peptide disclosed by Tseng et al is "substantially homologous" to the

claimed peptides. Furthermore, Applicant's claims also recite "derivatives of said peptide." Applicant's specification defines derivatives as "peptides with any insertions, deletions, substitutions and modifications..." (Page 19, lines 10-20). The full length protein disclosed by Tseng et al merely has a few amino acids "inserted" on the claimed peptide, and therefore Tseng et al teaches each and every limitation of the claims.

4. The rejection of claims 50-84 under 35 U.S.C. 102(e) as being anticipated by Dow et al (US 5,705,151, Jan 6, 1998) is maintained.

Applicant's are asserting that Dow fail to teach that a portion of the full length superantigen is capable of antagonizing toxin-mediated activation of T lymphocytes as claimed. Applicant's assert that the present invention, in contrast, teaches that a portion of an exotoxin (superantigen), i.e., a peptide that is not involved in binding of the toxin to the T-cell receptor or to MHC class II molecules, but forms the central turn in the toxin molecule starting with the β-strand 7 and connecting the β-strand 7, via β-strand 8, to α-helix 4, is capable of antagonizing toxin-mediated activation of T lymphocytes. Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view of the disclosure of Dow et al. Applicant's have acquiesced that Dow et al disclose of a full length protein, from which Applicant's are attempting to claim certain peptides. However, Applicant's claims are not commensurate in scope with Applicant's assertions. Applicant's claims recite an isolated and

purified peptide "having an amino acid sequence substantially homologous to an amino acid sequence..." The full length peptide disclosed by Dow et al is "substantially homologous" to the claimed peptides. Furthermore, Applicant's claims also recite "derivatives of said peptide." Applicant's specification defines derivatives as "peptides with any insertions, deletions, substitutions and modifications..." (Page 19, lines 10-20). The full length protein disclosed by Dow et al merely has a few amino acids "inserted" on the claimed peptide, and therefore Dow et al teaches each and every limitation of the claims.

Dow et al teach an isolated peptide having a amino acid sequence (SEQ ID NO:2) 99.8% identical to the claimed amino acid sequence of SEQ ID NO:12, which is completely identical to the claimed N-terminal and C-terminal structures because the complete identity sequences homolog at both N-terminal and C-terminal of the sequences of DOW and the instant invention. The peptide of Dow is capable of antagonizing toxin-mediated activation of T lymphocytes (column 3-4, lines 49-55). The peptide of Dow is the derivatives of the peptides from pyrogenic exotoxin having amino acid sequences of SEQ ID NO:1-12 and the peptide of Dow et al is substantially homologous to any one of the peptides of SEQ ID NO:1-12.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

March 19, 2001